Effectiveness of Dynamic Neuromuscular Stabilization Exercises in Patients of Non-Specific Chronic Low Back Pain with Movement Control Impairment

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Certificate

I hereby declare that the short synopsis "Effectiveness of Dynamic Neuromuscular Stabilization Exercises in Patients of Non-Specific Chronic Low Back Pain with Movement Control Impairment" being submitted in partial fulfillment of the requirement for the degree of Doctor of Philosophy in Physiotherapy under faculty of Allied Health Sciences of Manav Rachna International Institute of Research & Studies, Faridabad during the academic year 2020-2021

It is a bona fide record of original work carried out under the supervision of Dr. Irshad Ahmad and has not been submitted in full or part to any other university or institute for degree or diploma. Further, it is certified that short synopsis is plagiarism free and proof has been submitted.

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ABSTRACT

Background/Introduction: The outcomes of therapeutic exercises in the rehabilitation of non-specific chronic low back pain have been under review in recent times. Due to contradictions in previous study results and heterogeneity of these patients, pieces of evidence suggest to identify an effective treatment approach to which a specific homogeneous movement controls impairment (MCI) subgroup of non-specific chronic low back pain (NSCLBP) can have positive and consistent response.

Objectives: This study will examine and compare the therapeutic outcomes of Dynamic Neuromuscular Stabilization (DNS) with Strengthening and Flexibility Exercises (SFE) on lumbar segmental motion and all other clinical and functional measures like lumbo-pelvic dynamic stability, trunk endurance, proprioception, pain, disability, kinesiophobia and quality of life in patients of NSCLBP with MCI.

Method: It will be a prospective experimental study with 66 subjects chosen based on inclusion criteria and randomly assigned to one of the two groups (33 subjects in each group). Outcome variables will include lumbar segmental motion (sagittal plane intervertebral rotations and translations), lumbo-pelvic dynamic stability, trunk endurance, proprioception, pain, functional disability, kinesiophobia and quality of life. Both groups will receive progressive group specific exercises. Group A will receive DNS Exercises and Group B will receive generally prescribed strengthening and flexibility exercises (SFE) for 30-45 minutes per session. Participants will have supervised training preferably on 5 days in a week for a total of 6 weeks or altogether for total 30 sessions of treatment in consecutive weeks.

Expected Outcome: The expected result of the study will be that DNS group will show significant differences against strengthening and flexibility exercises (SFE) with improved lumbar segmental motion and all other related clinical and functional measures.

Key words: Dynamic Neuromuscular Stabilization (DNS), Strengthening and Flexibility exercises (SFE), Movement Control Impairment (MCI) and Non- Specific Chronic Low Back Pain (NSCLBP)

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1. Introduction

1.1 Definition, prevalence & clinical presentation of NSCLBP

Low back pain is a common global concern in health care since 1990 and remains the leading cause of years lived with disability (YLD) (Wu et al., 2020). Chronic low back pain (CLBP) is defined as persistent or frequently reoccurring disabling pain confined to the area between the twelfth ribs and the gluteal folds, with a reported duration of more than three months (≥ 12-week) (Airaksinen et al., 2006; Chou & Huffman, 2007; Treede et al., 2015). In the absence of a known patho-anatomical underlying cause or specific pathology, 85%-90% of chronic low back pain (CLBP) disorders are usually classified as non-specific chronic low back pain (NSCLBP) disorders (Balagué et al., 2012; Finucane et al., 2020; D. Hoy et al., 2010), Hence, less than 10% of LBP individuals do have an identifiable and specific cause of back pain like infection, spondylitis, tumors, osteoporosis, inflammatory diseases, fractures, radiculopathy, spinal stenosis, or cauda equina syndrome (Koes et al., 2006).

Worldwide, almost 50-80% of adult population tend to have lower back discomfort sometime in the course of their lives (Andersson, 1998; Rubin, 2007). The prevalence of LBP was estimated to be around 23%, rendering 11-12% of population being disabled (Airaksinen et al., 2006). With respect to years lived with disability (YLD), it was ranked highest in comparison to any other disorder and sixth in terms of overall burden (measured in Disability-Adjusted Life Year- DALYs) (Damian Hoy et al., 2014). LBP in adults remained to be amongst one of the leading causes for YLD in 2017 also, with an annual incidence rate around 17.5-30% (James et al., 2018). In the Indian context, the prevalence rate of CLBP is increased to 19.6% between 20 and 59 years individuals and found to be more prevalent in women between 30 and 60 years (Bindra et al., 2015).

The individuals with NSCLBP are reported to present with an altered feed-forward mechanism and neuromuscular impairment in terms of delayed and reduced efficiency of Transversus Abdominis (TrA) and Lumbar Multifidus (LM) muscles during repetitive trunk movements and dynamic limb activity (P.W. Hodges & Richardson, 1997; Paul W. Hodges & Richardson, 1997b, 1997a, 1999a, 1999b; Hodges PW, Richardson, 1996; Lindgren et al., 1993; Silfies et al., 2009). Further, such individuals are also found to have significant impairment of lumbo-pelvic stability with increased lumbar mobility or clinical lumbar segmental instability during the dynamic functional movements (Lakke et al., 2009; P. O'Sullivan, 2005; P. B. O'Sullivan, 2000) reduced endurance (Sung, 2013; Suzuki & Endo, 1983) and lumbar repositioning (proprioceptive) sense as a consequence of impaired motor functions (P. B. O'Sullivan et al., 2003; Sheeran et al., 2012, 2019). Among all the deep

stabilizers of the trunk, TrA and LM are the two important muscles that have been mostly investigated in the context of associated spinal instability and neuromuscular impairment in NSCLBP patients.

Previous literature indicates significantly altered recruitment patterns, activation asymmetry, decreased cross-sectional area (atrophy) and reduced thickness (at rest and contraction) of TrA and LM muscles in these patients (Ferreira et al., 2004; Pillastrini et al., 2015; Sánchez Romero et al., 2021). Apart from that, reduced thickness and excursion of diaphragm muscle have also been observed in CLBP patients (Calvo-Lobo et al., 2019; Kolář et al., 2012; Vostatek et al., 2013). Furthermore, Non-specific low back pain along with associated disability, fear of pain with movements (kinesiophobia) and reduced quality of life has been found to impact the emotional and cognitive status of these patients (Picavet et al., 2002; Ramond et al., 2011; Vlaeyen et al., 1995).

1.2 Chronification of LBP

Previous biomechanical investigations have indicated that mechanical loading may be a possible causative factor in the development of pain in lower back area (Kuiper et al., 2005; Solomonow et al., 2003). Pieces of evidence indicate that individuals with NSCLBP disorder might have imposed stress and strains under excessive and repetitive loading of spinal tissues during activities of daily life (Solomonow et al., 2003). Peripheral and central sensitizations are the two processes that have been related to the possible etiology of chronification of NSCLBP disorder (Graven-Nielsen & Arendt-Nielsen, 2010; Roussel et al., 2013). Excessive and abnormal mechanical tissue loading is thought to precipitate tissue injury that has not resolved beyond expected healing time (Panjabi, 2006) or even non-injurious ongoing mechanical stimulation of spinal tissues in the presence of maladaptive or aberrant movements may precipitate nociceptive inputs that are perceived as pain at higher center (Lynn & Perl, 1996; P. O'Sullivan, 2005). Central sensitization plays a critical role in pain persistence due to maintained peripheral nociceptive inputs even after natural tissue healing (Roussel et al., 2013). Moreover, over the time, pain persistence in NSCLBP disorder is also attributed to the influence of other psychosocial factors such as, kinesiophobia, stress and depression (Grotle et al., 2010).

1.3 Motor control impairment as an underlying mechanism of NSCLBP

Time, again and again, various evidences suggested that impairment of motor control and alteration in central nervous system could be considered as a predisposing factors and underlying mechanism for NSCLBP (Brumagne et al., 2019; Wim Dankaerts et al., 2009; P.W. Hodges & Richardson, 1997; Hodges PW, Richardson, 1996; P. O'Sullivan et al., 1997;

P. B. O'Sullivan, 2000). However, a cause and effect relationship could not be established because of the presence of the variability in motor control impairment among such individuals (P. O'Sullivan, 2005). Functional or clinical lumbar instability (CLI) has been underpinned as a potential mechanism or driver of NSCLBP (P. B. O'Sullivan, 2000; Panjabi, 2003, 2006). However, individuals with NSCLBP are suggested to lie on a broad spectrum of motor control impairment, ranging from clinical lumbar segmental instability to altered dynamic control of the spinal stabilizers muscles in the form of maladaptive aberrant movement behavior without any lumbar segmental instability (Comerford & Mottram, 2001; Mottram & Comerford, 2008; P. O'Sullivan, 2005).

Existence of motor control impairments related to in-coordination and instability of the spine has been linked with inefficient deep stabilizing muscle groups i.e. TrA and LM (P.W. Hodges & Richardson, 1997; Paul W. Hodges & Moseley, 2003; Paul W. Hodges & Richardson, 1997b; Jull & Richardson, 2000; Silfies et al., 2005). Furthermore, the lumbar segmental instability or movement coordination impairment in NSCLBP patients has been found to be associated with the presence of maladaptive movement control or aberrant movement patterns (Biely et al., 2014; Delitto et al., 2012). Hence, the overall clinical condition seems more complex and detrimental in the presence of aberrant movement patterns or maladaptive movement control of the spinal region because these patients can't control their movements properly and tend to injure themselves unknowingly and increase their pain and disability (P. O'Sullivan, 2005).

1.4 Movement control impairment (MCI): A largest subgroup of NSCLBP Disorder

The Multidimensional Clinical (MDC) framework (formerly known as O'Sullivan classification is a validated bio-psychosocial framework and classification system to categorize individuals with CLBP (P. O'Sullivan, 2005). Movement Control impairment (MCI) characterize the third and largest subgroup of this system as the primary source of pain in the population of NSCLBP individuals with an estimated occurrence around 30% in LBP patients (P. O'Sullivan, 2005). MCI patients may be characterized by the presence of pain in the lower back area that has been mechanically induced with associated secondary psychosocial compensation. Individuals under such category often present with postural pain and maladaptive movements like the uncontrolled movement of the lumbar segments in the primary direction of pain provocation without any deficit in physiological range of movement. Individuals with MCI dysfunction have five distinct direction specific pain provoking movement behavior such as flexion pattern (FP), Active and passive extension pattern (AEP & PEP), lateral shift (flexion or extension) (LSP) and multidirectional pattern.

The patients belonging to MCI subgroup usually perceive pain during dynamic and/ or static tasks (static postures). Among all the patterns, flexion and extension related MCI dysfunctions are the most commonly observed maladaptive postures and movement behaviors (P. O'Sullivan, 2005; P. B. O'Sullivan, 2000).

Pain among such individuals is suggested to be associated with loss of functional dynamic control of lumbar motion segments around its neutral zone i.e clinical lumbar instability, commonly as a result of specific motor control deficits in the spinal stabilizing muscles. Moreover, it has been also suggested that an altered and maladaptive movement control of specific regions of the spine may render the spinal tissues to be more vulnerable to excessive stresses and strains from abnormal loading and repetitive end range movements (P. O'Sullivan, 2005; P. B. O'Sullivan, 2000).

O'Sullivan's sub-grouping classification system is highly reliable and valid classification system and support the links between the altered muscle recruitment and direction related non-specific low back pain (Wim Dankaerts et al., 2006; Wim Dankaerts & O'Sullivan, 2011). Further, in order to indicate that motor control is impaired in MCI subgroups, Luomajoki evaluated several tests, of which a set of 6 MCI tests were found to exhibit significant reliability (Luomajoki et al., 2007). A healthy individual can be effectively differentiated from a patient with pain in the lower back by these tests (Luomajoki et al., 2008, 2010).

1.5 Motor Control or Specific Stabilization Exercises: Motor control intervention

Over the years, with the acceptance of the fact that the problem might be of altered neuromuscular control mechanism, the focus for therapeutic approach has been from a motor control perspective. Therefore, the modulation of neuromuscular control by adopting an effective therapeutic strategy was recommended based on the theory that lumbar spinal stability and control is altered in non-specific low back pain patients due to a lack of anticipatory spinal control mechanism (Hodges PW, Richardson, 1996).

With the same perspective of normalizing the motor control, the therapeutic stabilization programs such as motor control exercises or specific core stabilization exercises have therefore been developed and utilized in clinical practice and their efficacy was investigated in clinical research (Costa et al., 2009; Ferreira et al., 2006; Paul W. Hodges, 2003; Imai et al., 2010; Jull & Richardson, 2000; P. B. O'Sullivan, 2000). Although, over the past two decades of research, evidence remain contradictory and inconclusive and have not been shown to provide clinically meaningful changes in pain, function, or lumbar movements (Cleland et al., 2002; Hayden et al., 2005; Saragiotto et al., 2016; Smith et al., 2014; Van

Tulder et al., 2007). However, the explanations offered for the lack of evidence mainly relates to study designs with broad inclusion criteria, resulting in heterogeneous samples and static spinal stability oriented intervention protocols that disregarded the dynamic stability need unknowingly (Alrwaily et al., 2017; Saragiotto et al., 2016; Smith et al., 2014).

1.6 Stratification or considering homogeneity amidst heterogeneity of NSCLBP

Over the decades, homogeneity of CLBP patients has been recommended for effective outcomes strategies (Leboeuf-Yde et al., 1997; Van Dieën et al., 2019b). It was recognized that if such a considerably large group of NCSLBP patients had been assigned to a more homogeneous subgroup depending on certain justified criteria, such patients could have been treated in a quite effective manner (Gutknecht et al., 2015; Mohammadi et al., 2017; Saner et al., 2015). Shreds of Evidence support the notion that treatment of NSCLBP patients specifically targeted to a homogeneous population of MCI may improve the patient outcomes (Lehtola et al., 2016; Saner et al., 2015; Van Dieën et al., 2019a).

The subjects belonging to the MCI subgroup present with diversity in their motor control impairment presentation in terms of direction of provocative movement and related muscle activation pattern or spinal stability impairment (W. Dankaerts et al., 2006; Wim Dankaerts & O'Sullivan, 2011; P. O'Sullivan, 2005; Van Dieën et al., 2017, 2019b). As far as, associated functional spinal stability is concerned, the variability may range from increased to decreased level of stability across the five sub-classes of MCI subgroup (P. O'Sullivan, 2005). Hence, the normalization of movement control behavior along with enhancing the integration of spinal muscles (stabilizers and mobilizers) can be considered to be an appropriate and effective strategy for the reduction of abnormal loading forces across pain sensitive structures. This strategy is thought to favor the positive outcomes of intervention by reducing the pain, disability and improving neuromuscular control in individuals having NSCLBP (P. O'Sullivan, 2005).

1.7 DNS: As a postural and dynamic stability intervention

Dynamic Neuromuscular Stabilization (DNS) is a functional rehabilitation approach; based on neurodevelopmental kinesiology and neurophysiological principles of the maturing postural-locomotion system of a child with normal CNS maturation in the first year of life (Kobesova & Kolar, 2014; Kolar et al., 2013). The DNS approach targets dynamic spinal stabilization by emphasizing the co-activation of the integrated spinal stabilizing system (ISSS) (Frank et al., 2013). Dynamic stabilization of the spine is achieved through adequate intra-abdominal pressure (IAP), which is generated through the coordinated co-activation of deep (diaphragm-TrA/IO-pelvic floor-multifidus muscles) and superficial core muscles of the

ISSS (Frank et al., 2013; Noh et al., 2014). The synkinetic activation of ISSS functional unit is automatic or "subconscious".

DNS exercise program was developed by Vojta on the basis of the ontogenetic developmental positions (Frank et al., 2013). An effective diaphragmatic breathing in various developmental postures, leads to reflexive stimulation of all related muscles of deep kinetic chain eccentrically to produce IAP, sufficient enough to stabilize the spine during superimposed dynamic tasks and to prevent overloading of the joints (Cholewicki et al., 1999; Frank et al., 2013). It emphasizes the training of muscles in all aspects of their physiological functional roles (phasic movement and stabilizing functions) by placing the patient into positions of ontogenetic development. The DNS approach focuses on normal physiological respiratory pattern and avoidance of overloading compensatory movement behavior in various static or dynamic developmental postures or even while transiting between them. Optimal movement functions are triggered, as patient is cognitively oriented towards achieving the joint centration. Centrated joint position ensures the optimum congruent position and alignment so that joint supporting muscles can consistently work at mechanical advantage with maintained length-tension relationship (Frank et al., 2013; Kolar et al., 2013). Moreover, DNS exercises stresses on achieving the centration of chest, whole spine and pelvis while patient is guided manually and verbally in self–identifying own optimal stabilization and movement pattern strategy. This process might help in improving the self-body awareness perception in patients with MCI dysfunction (Kolar et al., 2013).

Available evidence indicate that DNS exercises have the potential to improve postural stabilization and dynamic control through cortical as well as subcortical neuroplasticity by both feedback mechanisms of explicit (conscious feedback) and implicit (subconscious/feed-forward) re-leaning processes, respectively (D. H. Kim et al., 2016, 2018). Since both of theses processes of motor learning are required for normal anticipated and non-anticipated postural adjustment and reactions to an initiation and execution of coordinated functional movements along with prevention of musculoskeletal injury (Haynes, 2003), the DNS approach can be considered to be an effective intervention to emphasize the efficient and coordinated movements that may mitigate compressive loading during dynamic and static or sustained postures (Frank et al., 2013).

1.8 Rationale of the Study

Dynamic Neuromuscular Stabilization (DNS) program seems to significantly optimize the activity of inefficient deep core muscles like TrA and lumbar multifidus with simultaneous balanced counterpart muscle activity for retrieving postural and dynamic

stability in patients having neuromuscular control impairment (N. G. Lee et al., 2018; Hyun S. Yoon & You, 2017; Hyun Sik Yoon et al., 2020). Moreover, in addition to the conscious feedback mechanism, DNS specifically has a subconscious (feed-forward) mechanism that activates and synergistically engages the postural stabilization cylinder belt, comprising of the abdominals, spinal extensors, diaphragm and pelvic floor muscles to generate adequate IAP (Frank et al., 2013; Kolar et al., 2013). Such generation of IAP to optimum levels optimizes the postural stability in response to internally as well as externally induced perturbations during dynamic limb movements (Cholewicki et al., 1999).

Further, to the best of our knowledge and surprise not a single study on the efficacy of DNS exercises in NSCLBP patients could be traced in literature, even when these patients do present with altered anticipatory postural adjustment (Paul W. Hodges & Richardson, 1999a, 1999b), and postural reactions to perturbations (Strutton et al., 2005) and reduced neuromuscular activation of trunk and extremities muscles (Tsao et al., 2011). Therefore, the dynamic stabilization with DNS exercises in enhancing lumbar segmental stability and all other associated clinical and functional measures remain unknown in patients of NSCLBP with MCI. Furthermore, it also remains to explore the therapeutic effects of DNS based stabilization training in comparison to generally prescribed strengthening and flexibility exercises (SFE) training while assessing NSCLBP patients with MCI for lumbar segmental motion and all other associated clinical and functional measures like lumbo-pelvic dynamic stability, trunk endurance, proprioception, pain, disability, kinesiophobia and quality of life.

2. Review of Literature

2.1 DNS: A novel tool to activate dynamic spinal stabilization strategy

(Frank et al., 2013): In this clinical commentary, the authors discussed the dynamic neuromuscular stabilization approach with the perspective of sports rehabilitation. Under the light of sufficient pieces of evidence, the author unfolds the promising potential of DNS throughout the commentary. According to the authors, the DNS approach not only provides a necessary functional tool for assessment but also optimizes the movement system by activating the spinal stabilizers. Under the light of sufficient shreds of evidence, the author unfolds the promising potentials of DNS. It was emphasized that the DNS approach can influence CNS for the accomplishment of core stabilization through precise muscular timings and coordination and intra-abdominal pressure regulation. Hence, DNS exercises activate the integrated spinal stabilization system (ISSS) by balanced co-activation of the trunk and extremities and coordinated IAP during static and functional (dynamic) postures.

Furthermore, the neuromuscular strategy of DNS is suggested to be dynamic in nature to provide functionally neutral or centred joints. The centrated joints allow the mechanical de-loading and de-stressing of passive structures such as ligaments, capsules, cartilages and joint surfaces.

(Kobesova & Kolar, 2014): The author of this study discussed and unfolds the stage-wise developmental physiology of a newborn (human ontogenetic model). Three levels of sensorimotor control are recognized within the central nervous system (CNS). The spinal and brainstem levels control a neonate's movements and primitive reflexes in the first 28 days after birth (first level). Emergence and maturation of next level of control i.e. subcortical level get completed in the first year of life (second level). This level of control is mainly responsible for core stability through balanced synergism of kinetic chain for the accomplishment of postural-locomotor function. It is emphasized that lower thoracic and lumbar spine stabilization is the outcome of a complex and balanced synergy among the diaphragm, pelvic floor, abdominal wall, and spinal extensors. Such stabilization is an induced effect of increased intra abdominal pressure in response to a synergistic concentric contraction of diaphragm and pelvis floor along with eccentric contraction of the abdominal wall in all directions. In ideal conditions, the low back is stabilized, as the activity of spinal extensors shall balance the abdominals in front with maintained IAP. The final level of motor control is the cortical level (third level), which emphasizes the individual movement characteristics, isolated segmental movement and relaxation.

2.2 Role of DNS exercises on posture and dynamic spinal stability in various conditions

(Ghavipanje et al., 2022): In this RCT, the authors looked at the benefits of DNS and general workouts in young obese postpartum women with LBP. The intervention was carried out six days a week. The NPRS, MODQ, breath hold time and respiratory rate, and Fear-Avoidance Beliefs Questionnaire (FABQ) were used to measure the pain, disability, respiratory functions, and patient's fear avoidance beliefs about physical activity and job, respectively. Patients in the DNS group improved at a faster pace than those in the general exercise group after six weeks of training.

(J. Lee et al., 2021): The researchers included a total of 41 persons with core instability in this experimental investigation with the goal of analysing the differential effects of three types of core stability maneuvres. In a random order, patients were instructed to perform ADIM , AB & DNS breathing. During the performance, ultrasound imaging was utilized to evaluate diaphragm descending movement and thickness of deep abdominals (TrA & IO), sEMG was used to assess external abdominal oblique (EO) EMG amplitude, and Simi

Aktisys motion capture system and PBU was used to analyse core stability.When compared to the other two, DNS breathing resulted in considerably greater diaphragmatic descending movement and TrA & IO muscle thickness. Furthermore, the IO amplitude increased substantially more with the AB manoeuvre than with the other two.

(S. Kim et al., 2017): The researchers of this small sized RCT compared the effects of 4 weeks training of ADIM (N=10) and Diaphragm breathing (N=9) in patients with chronic stroke. The thickness of TrA, IO & EO muscles, trunk control and balance was assessed with ultrasound imaging, Trunk impairment scale (TIS) and Berg balance scale (BBS), respectively. The results of study reported that both groups improved compared to respective baseline, whereas between group differences of TIS score was significantly higher in diaphragmatic breathing group compared to ADIM.

(Rahimi et al., 2020): The author of this 6 weeks RCT, evaluated the effects of DNS on thoracic kyphosis, chest wall mobility and trunk extensor endurance in 52 sedentary students having poor posture and 19-23 years age group. Measuring tape, extension endurance test and photogrammetry in sagittal left and right views for standing posture were used to assess the intended outcome measures. The study concluded that the group having DNS exercises was observed to have significant improvement in all outcome measures at the end of the intervention in comparison to control treatment.

(Mahdieh et al., 2020): The authors of this RCT investigated the dynamic neuromuscular stabilization impact on functional movements (FMs) in thirty-four non-athlete healthy female students. Functional movements were assessed by five basic functional tests at baseline and post-intervention. Subjects were randomly allocated into two matched groups of DNS and physical fitness (PF) training and received the 6 weeks exercise program (three sessions of 50 minutes weekly). The study revealed that DNS group progression was significantly higher than the physical fitness-training group for all five functional movements. Furthermore, large effect size indicated the effectiveness of DNS exercises for all five functional movements.

(Hyun Sik Yoon et al., 2020): The authors of this pretest-posttest study examined the comparative efficacy of DNS (n=16) and conventional NDT (n=15) exercises in sub-acute stroke individuals. Respective intervention to both groups was given for 30 minutes/session, 3sessions/ week x 4 weeks. Outcome measures of abdominal muscle thickness and Diaphragm movement were measured by ultrasound imaging, postural control with trunk impairment scale (TIS) and berg balance scale (BBS) and gait ability with functional

ambulation category (FAC). The study concluded with superior effects of DNS over NDT for all outcome measures except the TIS.

(Hyun S. Yoon & You, 2017): In this small-sized clinical trial study authors intended to observe the effects of DNS and NDT exercises in 5 healthy and 5 hemiparetic stroke individuals. Pressure biofeedback unit (PBU), surface EMG and ultrasound imaging were used to measure the core stability, muscular activity (Tr, IO, EO & RA) and thickness (TrA& IO) respectively. Results of the study were found to be in favor of DNS exercises both for healthy and hemiparetic stroke patients in all outcomes of interest.

(Son et al., 2017): The author of this clinical trial recruited fifteen subjects classified as spastic diplegic CP (7 females, 8 males). Patients were given an intervention of DNS exercises for 30 minutes/day, 3 days a week for 4 weeks. The GMFM-88, ultrasound imaging, and EMG signals has been used to examine the Gross motor function, diaphragm excursion, and muscle activation respectively. It was concluded that DNS improved the diaphragm descending movement, activation of deep core muscles (IO and TrA) and scores related to standing, walking and jumping domains of gross motor function measure.

2.3 DNS: Conscious and subconscious dynamic stability training

(D. H. Kim et al., 2016): In this single case, the experimental study design author explored the neural substrates underlying two types of core stabilization (CSE with ADIM Vs. DNS) exercise tasks in a 25 years old female having non-symptomatic core instability. Before the investigation, the participant's core instability was ensured with the ability to maintain target pressure level during active straight leg lowering test while using PBU. 3 T Functional MRI (fMRI) BOLD (Blood Oxygen-Level Dependent) signal recording was used for identifying the activated neural substrates during 4 exercise tasks viz. (1) conscious ADIM (2) conscious ADIM with hip flexion and extension (ADIM-HFE) (3) subconscious hip flexion and extension (HFE) and (4) subconscious DNS-based HFE with a period of rest in between. The study participant was trained for these exercise tasks for 30 minutes each day and three consecutive days before the experimental fMRI. Real-time ultrasound was used for ensuring the specificity of training. According to the study results the increased activity from subcortical neural networks mainly thalamus, basal ganglia, cerebellum, anterior cingulate and anterior insular cortices along with the contralateral primary motor area were noted during HFE and DNS-based HFE, whereas the contralateral primary motor area that topographically represents the trunk and legs was activated during the conscious ADIM and ADIM-HFE tasks. Hence, subconscious HFE and DNS-based HFE mediate implicit learning by selectively activating the subcortical motor control network whereas "voluntary"

conscious ADIM and ADIM- HFE motor tasks utilize cortical motor network for explicit learning.

(D. H. Kim et al., 2018): The author of this experimental study investigated the comparative efficacy of short duration conscious stabilization exercises in the form of ADIM and subconscious stabilization exercises in the form of DNS. The outcomes of both stabilization exercises were seen in terms of cortical alterations among adults with clinical lumbar instability. Enrolled participants (n=5) with clinical lumbar instability were without any symptoms. They practiced both the exercises for 30 minutes per day for three consecutive days. During both types of exercise, ultrasound imaging was used for real-time visual feedback while maintaining the targeted PBU. The results of fMRI blood BOLD analysis indicated the subcortical and cortical activation pattern during the DNS exercises, whereas the cortical motor networks were activated during ADIM performance.

(N. G. Lee et al., 2018): The author of this RCT evaluated the comparative effectiveness of DNS exercises and conventional CSE in chronic hemiparetic stroke patients (n=28). Patients of both groups underwent respective exercises for 30 minutes of session in a day for all 5 days in a week. Surface EMG during rapid shoulder flexion, Trunk Impairment Scale (TIS), Berg Balance Scale (BBS) and Falls Efficacy Scale (FES) were utilized to assess the anticipatory postural adjustment (APA) time of core muscle (IO, EO, TrA & ES), trunk movement control, balance performance, and fear of falling respectively. According to the results of the study, APA times for core muscles were shorter following DNS exercises in comparison with conventional exercises. Both groups improved in BBS, TIS scores and FES when compared with baseline scores. However, FES remained stable even after 2 years of follow up in the DNS group only.

3. Description of Broad area

3.1 NSCLBP and altered neuromuscular impairment

Low back pain (LBP), a common disorder with a high prevalence of chronicity (lasting more than 12-week duration) or frequent recurrences, is disabling and has a negative impact on one's quality of life. The 85%-90% of chronic low back pain (CLBP) disorders that cannot be classified for a known patho-anatomical diagnosis creates a diagnostic and management vacuum. In the population of concern, issue of altered neuromuscular control mechanisms impacting movement efficiency and trunk stability has been generally established over time.

With this perspective, the therapeutic interventions are recommended to target for achieving the efficient stabilization of the spine, normalization of neuromuscular control and normal patterns of the spinal motions. Further, while focusing on effective movement control and modulating the neuromuscular control, evidence supports enhancing dynamic stability through the specific and coordinated recruitment of deep and global muscular mechanisms. Over the last decades, the efficacy of therapeutic exercises has been called into question due to the absence of powerful evidence to support a certain specific exercise protocol that could provide the most superior and consistent results. Unfortunately, despite various therapeutic clinical trials no single intervention has been proven to provide satisfactory and complete relief in such patients.

3.2 Research Gaps

1. Over the last decades, though the effectiveness of specific spinal stabilization or motor control exercise programs has been established in the literature, there are lots of contradictions and variations in outcomes coming out through systematic reviews and Meta-analysis.
2. The efficacy of existing therapeutic exercises has been called into question due to the absence of powerful evidence to support a certain specific exercise protocol that could provide the most superior and consistent results.
3. According to literature, as far as NSCLBP patients with MCI subgroup are concerned, the distinct direction specific patterns are found to have variation in maladaptive motor activation recruitment and local lumbar segmental stability impairment. Better outcomes in response to any intervention have been suggested, if heterogeneity within the NSCLBP patients is being recognized using subgrouping and matched treatment is individualized.
4. Very few high-quality studies are available in literature wherein the therapeutic exercises have been provided to homogenous NSCLBP patients with control impairment.
5. DNS exercises are an effective and novel postural and dynamic spinal stabilization program in other musculoskeletal and neurological clinical conditions. However, its effectiveness has not been tested in NCLBP patients so far.
6. According to the principles of neuroplasticity, specific exercises lead to cortical reorganization. DNS exercises mediate both implicit and explicit learning by selectively activating the cortical as well as subcortical motor control network respectively in adults with spinal instability. However, such a promising spinal

stabilization strategy of DNS that can influence the feed-forward (subconscious learning) mechanism is yet to be explored.

3.3 Problem Statement

The effectiveness of neuromuscular trunk control is determined by its controller, the Central Nervous System (CNS). For any predictable movement, CNS controls and initiates a feed-forward response in the form of anticipated postural adjustments and synergistic activity of trunk and limb muscles prior to any afferent input from the intended movement.

NSCLBP patients present with neuromuscular impairment in terms of impaired movement control due to altered feed-forward mechanism and associated clinical lumbar instability with impaired recruitment and activation of spinal stabilizing muscles, pain and disability. DNS as a postural and dynamic spinal stabilization approach can be an alternative functional dynamic stabilization intervention to tap the conscious as well as the subconscious (feed-forward) mechanism in the population of concern. It seems to challenge the deep and global core muscles to significantly improve muscle control efficiency and other associated functional outcomes. The intended study is an attempt to evaluate the efficacy of DNS in comparison to general SFE exercises in NSCLBP patients with MCI.

3.4 Research questions

1. Will the DNS exercise be effective in decreasing the lumbar spine segmental instability in NSCLBP patients with MCI?
2. Does the DNS exercise effective in improving the pain, functions and quality of life in patients of NSCLBP with MCI?
3. Are there any differences in Lumbo-pelvic dynamic stability, trunk endurance and proprioceptive sense of NSCLBP patients with MCI when provided with the DNS exercise?
4. Will DNS exercises be effective in reducing movement related fear (Kinesiophobia) in NSCLBP patients with MCI?
5. In NSCLBP patients with MCI, is DNS control training superior to commonly prescribed strengthening and flexibility exercises (SFE) for improving the lumbar spine segmental stability and all other related clinical and functional measures such as lumbo-pelvic dynamic stability, trunk endurance and proprioception, pain, disability, kinesiophobia, and quality of life?

4. Objectives of Study

1. To measure the effects of the DNS exercises in improving the spinal neuromuscular control subsets such as lumbar segmental motion, Lumbo-pelvic dynamic stability, trunk endurance and proprioceptive sense in patients of NSCLBP with MCI.
2. To evaluate the effect of the DNS exercises on pain, functional disability and Quality of Life in patients of NSCLBP with MCI.
3. To measure the outcomes of the DNS exercises on psychosocial impact in the form of kinesiophobia in patients of NSCLBP with MCI.
4. To compare the changes in the above-mentioned parameters brought about by DNS exercises with strengthening and flexibility exercises (SFE) in patients of NSCLBP with MCI.

5. Methodology

5.1 Sample

Patients with chronic low back pain of more than twelve weeks visiting the Physiotherapy department of Pt. Deendayal Upadhyaya National Institute for Persons with Physical Disabilities (PDUNIPPD) will be included in the study.

5.2 Sample Size

A sample size calculation was determined by difference between two independent means (two groups) using the G-Power version 3.1.9.2, while considering the post-test data changes in NPRS as obtained in a similar clinical trial (Puntumetakul et al., 2021). The estimated total sample size came out to be 52 (26 in each group) while using the 2 tailed hypothesis, effect size of 0.80, alpha level 0.05, power of 80% and allocation ratio (N2/N1) of 1. Further, considering the probability of 20 % drop out, 66 patients will be taken as the total sample size.

5.3 Study Design

The intended study will be an assessor-blinded, experimental, randomized controlled trial with two parallel arms and two measurement points: baseline assessment and at the end of the six-week/30 sessions intervention.The subjects will be randomly allocated to the experimental (DNS) and control groups (SFE) using block randomization, with a block size of two and an allocation ratio of 1:1. Using sequentially numbered, sealed and opaque envelopes will ensure the concealment of allocation.

Ethical approval for the same will be sought from the Ethics Committee for Human Research at MRIIRS as well as from the Institutional Research Ethics Committee of

PDUNIPPD, New Delhi. This trial will be prospectively registered with the Clinical Trial Registry India (CTRI).

5.4 Inclusion Criteria

1. Both male and female patients having Chronic Low back pain, not attributable to any specific pathology (≥ 12 weeks)
2. Age group between 18-45 years.
3. ≥2 on Numeric Pain Rating Scale (NPRS) (Childs JD et al., 2005)
4. Positive prone instability test (Hicks et al., 2003, 2005)
5. Two or more positive test findings on Luomajoki MCI tests battery (Luomajoki et al., 2007) as well as MCI specific complaints of pain elicitation in static postures (Wim Dankaerts & O'Sullivan, 2011)
6. ≥20% on the Oswestry Disability Index version 2.1a (ODI v 2.1a)

5.5 Exclusion Criteria

1. Back discomfort caused by a specific pathology, such as a disc herniation, tumour, infection, or fracture, osteoporosis, structural deformity, inflammatory illness, radicular syndrome, or cauda equina syndrome.
2. Lower Back pain that is constant or severe, as determined by clinical criteria, due to nerve root irritation.
3. Any Spinal surgery or Major surgery within the past years.
4. Current Pregnancy or post partum period < 6 months and a multiparous woman who has given birth more than twice.
5. BMI ≥ 30 Or Presence of co-morbidity (e.g. history of angina, shortness of breath, uncontrolled hypertension), which may limit exercise performance.
6. Straight Leg Raise (SLR) < 50° Or positive sacroiliac-joint pain provocation tests.
7. Patients with a score of ≥ 72 on the Örebro Musculoskeletal Screening Questionnaire -12 (OMSQ-12) to avoid confounding by psycho-social factors (Gabel et al., 2013; Khan et al., 2021)

5.6 Variables

A. Independent Variables

1. DNS Exercises (DNS)
2. Strengthening and Flexibility Exercises (SFE)

A. Dependent variables:

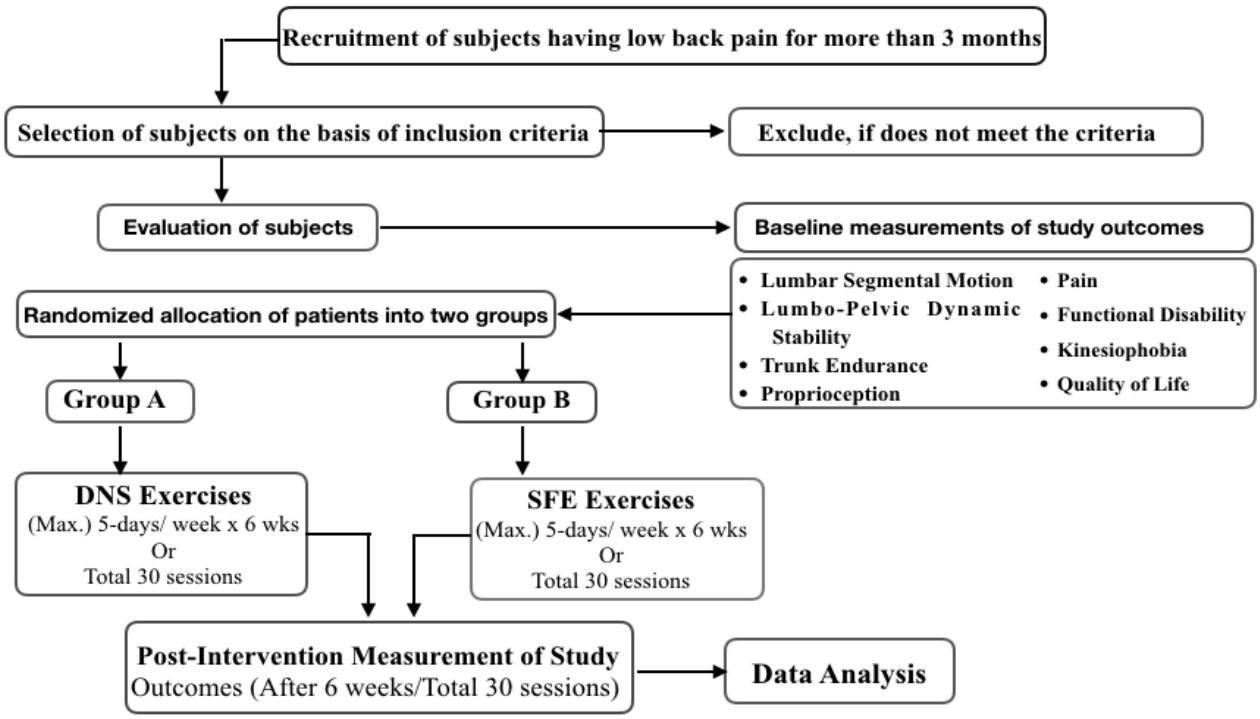
1. Lumbar Segmental Motion
2. Lumbo-pelvic Dynamic Stability

3. Trunk Endurance
4. Proprioception
5. Pain
6. Functional Disability
7. Kinesiophobia (Fear of Movement)
8. Quality of Life

5.7 Procedure

Patients attending the outpatient setting of the physiotherapy department of PDUNIPPD (Divyangjan), New Delhi will be recruited for baseline screening first. Participants who qualify for the baseline screening and NSCLBP eligibility criteria of the study will be required to sign an informed consent form before participation. The eligible participant will undergo a baseline (pre-intervention) measurement for study outcome measures. After this, participants will be randomly divided into experimental (Group A) and control groups (Group B) by using block randomization with concealed allocation. Participants of group A will receive the DNS (Dynamic Neuromuscular Stabilization exercises), whereas group B will have SFE (Strengthening and Flexibility Exercises) preferably on 5 days a week for a total of 6 weeks or altogether for total 30 sessions of treatment in consecutive weeks. Post-intervention measurement for study outcomes will be taken after 30 sessions.

5.8 Protocol



5.9 Interventions

Study participants will be attending the physiotherapy department setting on all working days of the week regularly throughout the study duration. The patient will be supervised, instructed, and manually guided by the therapist throughout the therapy session while ensuring the specificity of exercises. Exercise protocols will be adhered in terms of the progressions. However, individualized pacing will be done. All patients will be engaged in 30-45 minutes of group specific exercise sessions preferably for 5 days a week, for a total of 6 weeks or altogether for 30 sessions of treatment in consecutive weeks of study duration. There will be a total of three phases of exercises throughout the duration of the study in both groups. The patient will only advance to the next phase after two weeks of consistent exercise, once they have mastered the optimum control of previous exercises and feel comfortable with them.

With the cognitive aspect influence in mind, the first session for all patients in both groups will include an additional 10 minutes of time to educate them about the involved core muscles in spinal stability, their weakness impact on back pain, and the retraining effects of group specific exercises in terms of pain reduction and reoccurrences of back pain symptoms. Patient's education will remain the integral part of the treatment in both the groups.

1. **Dynamic Neuromuscular Stabilization (DNS) Exercises**

Patients enrolled in DNS specific exercise group will be trained for various progressive DNS approach based postural and dynamic stabilization exercises throughout the 6 weeks of training. Exercises will mainly include diaphragmatic breathing, static and dynamic postures of Baby Rock (supine 90-90), Prone, Rolling, Side Lying, Quadruped, Oblique Sit, Sitting, Tripod Stance, Standing Squat, Bear posture and transitions between the immediate developmental postures. Patients performing DNS exercises will be trained initially for diaphragmatic breathing at rest with proper instructions of breathing into the entire circumference of lower abdomen without holding the breath and allowing the rib cage to lift cranially and out. During the diaphragmatic breathing maneuver, an experienced therapist (primary investigator) will provide proper tactile cues by placing the hands around the lower abdominal and inguinal area or by manually directing the rib cage caudally. While breathing in against the therapist's hand, the intra abdominal pressure will be maintained by the patient by not allowing the abdomen collapse especially during expiration. Diaphragmatic breathing will be practiced correctly and maintained for 5 sec (Frank et al., 2013).

Exercise progression has been adapted and modifies from the published DNS exercise protocol of Mahdieh et al., 2020. Once the patient is trained successfully for DNS

diaphragmatic breathing, the overload principle will be implemented by making the exercises more complex. Exercises will be progressed by including the next level of developmental postures and single or bilateral extremity movements, either of ipsi-lateral or contra-lateral sides in ipsi-directional or contra-directional manner (Mahdieh et al., 2020). Furthermore, patient will be instructed to perform such movements with specificity in a slow and coordinated manner while regulating the diaphragmatic breathing and IAP. Throughout the therapy session, the therapist will visually and manually inspect the exercise performance.

2. Strengthening and Flexibility Exercises (SFE)

Patients participating in SFE group will be trained for basic Strengthening and flexibility exercises with an emphasis of improving the strength of all of the trunk muscles and improving trunk and lower limb flexibility in all planes as per the designed protocol of Van Dillen et al., 2021. All exercises are prescribed and progressed based on American College of Sports Medicine guidelines (Van Dillen et al., 2021).

The whole therapy session will be guided and supervised by the therapist and errors in performance will be corrected with appropriate feedbacks.

5.10 Outcome measures

A. Primary Outcomes

1. Lumbar Segmental Motion

Digital X- ray method is a known gold standard to detect lumbar segmental instability. Lumbar spine sagittal translation and rotation of lumbar spinal segments (L3-L4, L4-L5 & L5-S1) will be measured by full flexion and extension X-ray films in patients' side lying position according to criteria proposed by Punjabi in 2003 (Panjabi, 2003).

2. **Lumbo-Pelvic Dynamic Stability**

A reliable and valid device of Chattanooga Stabilizer (Chattanooga) will be used to assess the lumbo-pelvic stability (D Wohlfahrt, G Jull, 1993). The stabilizer is a pressure biofeedback unit (PBU) that indirectly records the degree of lumbopelvic stability and activation efficiency of deep abdominal muscles in terms of pressure change with lower extremity movement (Azevedo et al., 2013).To initiate with the test, PBU will be placed horizontally in lower lumbar area at the intersection of the inferior border and the posterior superior iliac spine with preset pressure of 40 mm Hg. Following the Liebenson et al., 2009, patient will be asked to perform the right supine active straight leg test (ASLR) to 20 cm elevation from the supporting surface while keeping the left lower extremity flat on the surface (Liebenson et al., 2009). Variation in the pressure in response to the ASLR will be recorded. Average of two readings will be considered as final reading.

3. **Trunk Endurance**

Endurance tests are the most reliable measures of trunk muscle endurance, with reported reliability (ICC) ranging from excellent (0.93–0.99) (McGill et al., 1999) high (0.82–0.98) (Evans et al., 2007) and moderate to very high (0.66–0.96) (Waldhelm & Li, 2012). The flexor, extensor, and bilateral side bridge tests, which measure the endurance of the anterior, posterior, and lateral trunk muscles, respectively, are the most common endurance tests. Participants will attempt to maintain the up supported static trunk position for a period of time during all three tests. Holding Time will be recorded with the help of a stopwatch. Average of 3 trials will be taken as final value.

4. Proprioception

Lumbar spine repositioning error will be determined by using a reliable and valid iPhone® application based inclinometer (ihandy© level application) (Caña-Pino et al., 2021; Kolber et al., 2013). During the assessment blindfold patient tries to reproduce a specifically given target angle of lumbar motion. Patient is made to sit on a fixed height stool keeping the hip and knee at 90-90 position and hands placed on thighs. The iphone® will be placed laterally just above the iliac crest, between the anterior and posterior superior iliac spines. Patient will be placed passively by the evaluator to a 30^0 lumbar flexion as a target angle. This target position will be sustained for 10 seconds and patient is instructed to remember this target position before the active return to initial position. Later, the value of actively achieved position will be recorded for recoding the deviation in subsequent repositioning attempts (Sheeran et al., 2012). Average of three trials will be taken as a final reading.

B. Secondary Outcomes:

1. Pain Intensity

The Numeric Pain Rating Scale (NPRS) is a 10-point valid and reliable scale that ranges from 0 to 10, indicating the severity of pain. The score of 0 is denoted as no pain, 1-3 as mild, 4-6 as moderate and 7-10 as severe pain. While rating, patient will be asked to mark or select the number that better defines his/ her intensity of pain. As a measure of pain intensity, the responsiveness as well as the concurrent and predictive validity of NPRS has been found to be satisfactory in LBA patients (Childs JD et al., 2005).

2. Functional Disability

a) Oswestry Disability Index (version 2.1a)

A commonly used self-administered questionnaire will be used to measure the associated functional disability of chronic LBP patients. ODI 2.1a is the valid and reliable

measure for assessing the constraints of various daily tasks. A greater score signifies a higher level of disability. The total score ranges from 0 to 100 (Baker et al., 1989; J. C.T. Fairbank et al., 1980; Jeremy C. T. Fairbank & Pynsent, 2000; Stokes et al., 2017).

b) **Patient-Specific Functional Scale (PSFS)**

PSFS will be used to determine and measure the patient's three most concerned pain-related functional activity limitation. PSFS ranges from points 0-10. 0 (Zero) point indicates no limitation in a defined activity means that patient can perform the concerned activity at the same level as before the back problem and 10 points indicates complete limitation (Stratford et al., 2000).

3. Kinesiophobia (Fear of Movement)

Kinesiophobia will be assessed using the valid and reliable Fear Avoidance Belief Questionnaire (FABQ). It is a 16-item self-report questionnaire used to assess low back pain patients' pain related fear and consequent avoidance of physical activity. Patient rates the agreement with each statement on a 7 point Likert scale; where 0 equates to completely disagree and 6 to completely agree (Panhale et al., 2019; Waddell Gordon et al., 1993).

FABQ has two subscales; the work subscales (FABQ-W) and the physical activity subscale (FABQ-PA). There is a maximum score of 96 and a higher score implies a higher level of fear of movement.

4. **Quality of Life**

36 items Short Form survey (SF-36) version 2, a valid and reliable scale will be used to evaluate the patient's perspective of his/ her functional health and well-being. It has 36 questions to assess the patient's physical and mental health under 8 health domains (Maruish, 2011; J. E. Ware, 2000; John E. Ware & Sherbourne, 1992). Summated raw response score will be transformed into 0 - 100 level range (Level 0 denotes the worst and 100 the best). Higher score value represents the good quality of life and better health status.

6. Expected outcome of the study

Hypothesis:

It is hypothesized that in NSCLBP patients with MCI, treatment with dynamic neuromuscular stabilization exercises (DNS) will result in significant outcomes of neuromuscular control subsets and all other related clinical and functional measures compared to general strengthening and flexibility exercises (SFE).

A. Experimental Hypothesis:

1. There will be significant improvement in lumbar segmental motion, Lumbo-pelvic dynamic stability, trunk endurance and proprioceptive sense at 6 weeks or total 30 sessions with DNS exercises in adults with NSCLBP and MCI as compared to those who will be receiving general strengthening and flexibility exercise (SFE) program.
2. There will be significant reduction in pain intensity, functional disability and kinesiophobia along with improved quality of life at 6 weeks or total 30 sessions with DNS exercises in adults with NSCLBP and MCI as compared to those who will be general strengthening and flexibility exercise (SFE) program.

B. Null Hypothesis:

1. There will not be any significant differences in lumbar segmental motion, Lumbo-pelvic dynamic stability, trunk endurance and proprioceptive sense at 6 weeks or total 30 sessions with DNS exercises in adults with NSCLBP and MCI as compared to those who will be receiving general strengthening and flexibility exercise (SFE) program.
2. There will not be any significant differences in pain intensity, functional disability and kinesiophobia along with improved quality of life at 6 weeks or total 30 sessions with DNS exercises in adults with NSCLBP and MCI as compared to those who will be general strengthening and flexibility exercise (SFE) program.

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